Claim Rejections under 35 USC 102/103

Claims 1-5, 10-11, 15, 17 and 22 stand rejected under 35 U.S.C. 102(b), the Examiner contending that such claims are anticipated by Schulman (US patent no. 4,071,032), hereinafter '032. It is the Examiner's contention that "...Schulman '032 discloses an elongated hollow tube formed of ferrite..." and that "...Schulman discloses a metal ferrite can 55...", The Examiner considers the hollow cylindrical tube claimed by Applicant as being the "metal ferrite can 55" of '032, which assuredly contradicts the express language and teaching of '032.

Indeed the Examiner cannot redefine that which is expressly provided by a reference. The metal can 55 of '032 is just that, a metal can, and it is not formed of ferrite as the Examiner contends. Any ferrite like qualities the Examiner assigns to metal can 55 is by way of the addition of other materials such as ferrite slabs placed in contact with the surface of the metal can 55. See '032 col. 10, lines 12-15 and in particular lines 21-35 and 52-56. The metal can 55 cannot alone provide the advantageous effects of the magnetic field concentrating material of Applicant's claimed invention. Since the metal can 55 is not taught as being a magnetic field concentrating material, an approach to providing a magnetic field concentrating effect taught by '032 is to add a second material such as a ferrite slab or coating on the metal can 55. As with the ferrite slab approach, the coating creates an overall two layered component assembly, rather than the single component assembly claimed by Applicant. The inventive concept of the single ferrite tube comprising a magnetic field concentrating

material brings with it decided advantages in manufacturing ease, reduced size, reduced cost and increased utility, not achievable with '032. In such regard, similar to the ferrite slab approach, a ferrite coating does not render the metal can as being formed of a magnetic field concentrating material, as contended by the Examiner. Schulman, Applicant notes, expressly provides otherwise. Even if a ferrite coating, having a thickness equivalent to that of the claimed invention, were applied to the metal can 55 as taught by '032, the overall dimension of the coated can could not achieve the outer diameter dimension of the hollow cylindrical tube due to the necessary addition of the thickness of the metal can. This is particularly critical since the housing design requirements demand an extremely small size to accommodate implant by a hypodermic needle type implantation tool to minimize patient discomfort during implantation. (See attached Declaration of G. Jiang.)

The Examiner further contends that it would obvious to one of ordinary skill to modify the metal can 55 of '032, such that it is a cylindrical tubular shape, having small dimensions. Even though the Examiner is undertaking impermissible hindsight reconstruction to redesign and modify '032, so as to develop the structure claimed by Applicant, such reconstruction still fails, since the metal can 55 cannot read completely on the hollow cylindrical tube formed of a magnetic field concentrating material.

Accordingly, despite the intended alterations to metal can 55, Applicant claims nevertheless still patentably distinguish over the '032 patent either taken singly or in combination with the other cited references.

With regard to claim 5, it is the Examiner's contention that the pacemaker circuitry described in '032 may be mounted on an appropriate support structure, as has

been argued above. Schulman '032 discloses a pacemaker can and does not disclose nor suggest an interior region of a hollow cylindrical tube formed of a magnetic field concentrating material. Since there is no equivalent structure in '032 relative to the hollow cylindrical tube, the circuitry within the metal can 55 cannot be a disqualifying teaching regarding the circuitry contained within the hollow cylindrical tube claimed by Applicant. Accordingly, claim 5 is patentably distinguishable over '032.

With regard to claim 11, it is the Examiner's contention that Schulman '032 discloses RF transmission and receiver circuitry, wherein the coil serves as an antenna, citing '032, col. 11, lines 26-33. The language cited by the Examiner as well as the preceding sentence is provided below for the Examiner's convenience:

> Hereinbefore a single coil 37 is shown wound about metal can 35 (see FIG. 5) or about block 55 together with the ferrite slabs 58 and 59, as shown in FIG. 7. The coil 37 was assumed to be the pickup coil for battery recharging. In practice, if the pacemaker is of the type which transmits or receives alternating magnetic signals from the body exterior, one or more coils, serving as transmit and/or receive coils or antennas, may be wound about the ferrite slabs and block 55, in addition to the battery recharging pickup coil. The additional coil or coils may be wound along the same axis as coil 37 or about any other axis.

As claim 11 recites, the coil and there is only one coil claimed, is: "...adapted to communicate with the RF circuitry as an antenna therefore...". Claim 10 provides that the coil is used to recharge the rechargeable battery. Accordingly, only one single coil is claimed by Applicant and such coil is multi-functional. The cited language describes the coil serving as an antenna as being an additional coil and further, that the additional

coil or coils may be wound along the same axis as coil 37 or about any other axis. The additional coil(s) wrapped around the hollow cylindrical tube would increase the overall size of the housing and therefore '032 teaches away from Applicant's smaller sized single coil arrangement. Since '032 teaches multiple coils, that is, a coil for each separate function, as distinct from Applicant's single coil, '032 neither anticipates nor renders claim 11 as obvious and the rejection of claim 11 should be withdrawn.

Regarding claims 15 and 22, the Examiner engages in mere impermissible speculation in considering several coil turns ('032, col. 7, lines 42-43) to anticipate the lower end of Applicant's range. Conventionally, "several" is taken to mean two or three, but not many. (See the American Heritage Dictionary of the English Language, fourth edition, 2000.) In such case, and at best, three turns is a mere 30 percent of Applicant's lower end coil turn count, which provides no support for a rejection based upon anticipation. Thus, '032 does not provide a range of turns, but merely a single valued number of several turns for its coil. The Examiner then goes on to refer to Schulman '367, which again discloses a single valued number of 200 turns for its coil, the Examiner taking such number as an upper limit of the coil turns and in the process, changing a single small number to a single large number to "define" a range. Neither reference defines a coil range, only a single valued coil turn number. In the first instance, the Examiner defines the coil turn number to suit the purposes of challenging Applicant's low range value of coil turns, and in the second instance, redefines the low coil turn number to a higher coil turn number to suit the purpose of challenging Applicant's upper range value of coil turn number. Neither the '032 nor the '367 reference refers to a range. The Examiner is trying to have it both ways, by redefining

coil turn numbers at will to suit the purpose at hand. This is inconsistent and using Applicant's claimed range as a basis for impermissible hindsight reconstruction. Moreover, even with the inconsistent, as you go redefining of coil turn number, neither reference even comes close to Applicant's claimed range. The Examiner takes the position that it would have been "...obvious to modify the microstimulator of Schulman '032 to include approximately 200 turns as taught by Schulman '367 in order to provide the necessary inductance...". Applicant includes no discussion nor claims regarding necessary inductance for its coil, accordingly, the Examiner's reliance on the "necessary inductance" provided by a 200 turn coil has no relevance to Applicant's claimed invention. Besides the impermissible redefining of terms, the Examiner's redefinition of 200 turns falls way short of Applicant's upper range coil turns of 600, 200 turns being a full 1/3 of Applicant's upper range.

Claim Rejections – 35 U.S.C. 103(a)

Claims 6 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 as applied to claim 5 in view of Schaldach, Jr. (US Patent No. 6,245,092), Schaldach '092 relates to pacemakers and defibrillators ('092, col. 2, lines 15-17). The interior volume of such devices is substantially larger, even by orders of magnitude than the hollow cylindrical tube claimed by Applicant. The hollow cylindrical tube of Applicant's invention has an inside diameter of 1.78 mm and an axial length of about 3 mm. The haphazard placement of parts with large voids between the various parts (see Fig. 3 of Schaldach) on a relatively large substrate, used in pacemakers and

defibrillators does not provide a teaching for the closely packed circuit configuration claimed by Applicant in the subsized hollow cylindrical tube also claimed by Applicant.

Moreover, the rejection of claims 6 and 7 is based on the applicability of '032 against claim 5. As was previously argued, for at least claims 1-5, '032 does not render such claims as unpatentable and accordingly, claim 5 is considered patentable along with claims 6 and 7, which depend from claims 5 and 6, respectively.

Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 as applied to claim 5, in view of Jeffcoat (US Patent No. 4,333,469). Consistent with the arguments set forth above, for the inapplicability of Schulman '032 for at least claims 1-5, here too, the combination of '032 and Jeffcoat '469 is equally inappropriate. Accordingly, claim 8 is considered patentable. Moreover, the field of Applicant's invention is implantable medical devices, in particular to remedying neural and muscular deficiencies, as is described in the background of the invention, and with particular reference to microstimulators described in US Patent No. 6,208,894. Accordingly, one skilled in the art would not go to the bone growth art, for which Jeffcoat is directed, to seek teaching regarding neuromuscular stimulation and a potting matrix. It is true that the title of '469, i.e., Bone Growth Stimulator, includes the word "Stimulator", but that alone is certainly not dispositive. There are other implantable stimulators not in Applicant's field, such as, for example, stimulators for the treatment of gastrointestinal disorders, US Patent No. 6,591,137, which also would not serve as an appropriate reference.

Furthermore, as clearly stated in the Abstract of '469 cited by the Examiner, the potting material is directed to preventing ionic contamination, which is a far less rigid

requirement, than hermeticity. Accordingly, the skilled person would not consult '469, since the objective of preventing ionic contamination, would not satisfy a much stricter and more strenuous requirement of hermiticity.

Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032 in view of Jeffcoat '469, as applied to claim 8, and further in view of Schulman US Patent No. 6,164,284. As previously argued with regard to at least claims 1-5 and those claims depending therefrom, '032 is inapplicable as an appropriate reference and accordingly, the combination of '032, Jeffcoat '469 and Schulman '284 is also inappropriate.

Claims 12-14, 16, 18-21 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman '032, as applied to claim 1, in view of Schulman '367. Inasmuch as it has been argued that Schulman '032 is not applicable as a reference against at least claim 1, then also is the combination of '032 with Schulman '367, also not applicable as a reference applied to claims 12-14, 16, 18-21 and 23. Furthermore, it is the Examiner's contention that it would have been obvious to modify the "microstimulator of" '032 to include tube and sleeve dimensions that allow for overall "microstimulator" dimensions taught by Schulman '367. Schulman '032 relates to a pacemaker 10 shown in simplified diagram form in Fig. 1. (See also '032, col. 3, lines 29-30, 44-45.) The "metal can" 55 shown in Fig. 7 as referred to by the Examiner is also a pacemaker. (See '032, col. 10, lines 28-35.) Accordingly, the teaching of metal can 55 in simplified form is that of a pacemaker.

Enclosed for the Examiner's convenience in Appendix A, are four patents, i.e., US Patents 5,176,136; 5,480,416; 5,545,188 and D478,990 dating form 1993 to 2003.

These patents are representative of traditional and conventional pacemaker can shapes and configurations. In no case may the pacemakers shown in the example patents be realistically considered, as contended by the Examiner, an elongated hollow cylindrical tube, especially in light of the added limitation of the tube being cylindrical. To do so, would be to impermissibly redesign '032 using Applicant's disclosure as a template and road map. In the Examiner's response to Applicant's arguments dated 3/27/06, the Examiner contends that it would be obvious to modify the metal can 55 disclosed in '032, such that it is cylindrical and tubular shaped, having the very small dimensions of Schulman '367 for easy implantation through the lumen of a hypodermic needle. Such contention is completely unsupportable, when considering the differences in the prior art as required by Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966) or the suggestion or teaching rule required by Teleflex, Inc. v. KSR, Intl. Co. 119 Fed. Appx. 282 (Fed. Cir. 2005). Teleflex requires a finding of a specific understanding or principle that would have led a person skilled in the art to make the combination in the particular manner claimed by the patent. When considering the metal can 55 in light of the express teachings of '032, one must look at a pacemaker to start the inquiry. In view of the enclosed example patents, a skilled person could not be motivated nor is there any teaching nor any evidence whatsoever in '032 to direct the person to implant a "pacemaker" through the lumen of a hypodermic needle, as the Examiner contends. (See attached Declaration of G. Jiang.) To do so, there must be a complete and total redesign of the pacemaker metal can disclosed in '032 using Applicant's claimed invention as a blueprint for such impermissible redesign. The

redesign of '032 with dimensions modified in accordance with '367 to arrive at Applicant's claims 12-14, must use Applicant's size and dimensions as a guide.

The Examiner has not established the required evidentiary component, but rather has relied on mere broad conclusory statements, rejected by the above noted cases. The foregoing, of course, is applicable to all obviousness rejections using at least Schulman '032.

It is recognized that relative scaling up or down in size or modest change in shape have been considered not sufficient to potentially distinguish over the prior art. However, those instances only arise when the claimed invention having the relative dimensions and shapes of the prior art device, would not perform differently than the prior art device. From the arguments set forth above regarding the patentability of the claims as presented, it is readily apparent that a mere change in dimension of the device of '032 would cause such device to perform differently than the claimed device. In such case, Applicant's claimed invention patentably distinguishes over '032 taken singly or in combination with the other cited references. (See Gardner v. TEC Systems, Inc., 725 F. 2nd 1338)

With regard to claim 16, the Examiner takes "about 44 gauge" to equal 51 gauge in order to provide the necessary inductance and to minimize any increase in the diametric dimensions necessitated by the coil. As mentioned previously, inductance is a concern not addressed by Applicant and therefore using inductance as the basis for the claim rejection has no relevance to the claims as presented. There is also no basis for the Examiner to consider "about 44 gauge" to be equal to 51 gauge. The Examiner engages in unsupported speculation as to the necessary inductance provided by the 51

gauge coil dimension. Indeed and advantageously, a 44 gauge wire has a greater current carrying capacity than does a 51 gauge wire. Moreover, a 51 gauge coil has a greater overall capacitance value than a 44 gauge coil, when wrapped around a ferrite tube, because it would be more closely packed about the ferrite tube. Accordingly, based at least on electrical engineering principles, the skilled person would not look to '367 or 51 gauge wire because of the inferior operating characteristics caused in part by the increased capacitance value, when compared to 44 gauge wire, which combines enhanced performance at an acceptable diameter size over the 51 gauge wire.

Still another important distinction negating the applicability of '032 relates to the size of pacemakers versus the size of the claimed invention. The Examiner's position is that "...said hollow tube defining an interior region thereof for housing corresponding microstimulator electronics. Schulman discloses a metal ferrite can 55 which houses the internal components of a pacemaker, except for the externally wound coil..." (emphasis added) The Examiner, as is best understood from the foregoing, equates the interior region of a pacemaker in an equivalent fashion with the interior region of the claimed hollow cylindrical tube to contain electronics. The claimed hollow cylindrical tube has an inner diameter of about 1.78 mm and a length of about 3 mm, which defines a volume of about 30 cubic millimeters. Enclosed for the Examiner's convenience in Appendix B, are product descriptions for selected pacemakers, namely Frontier, Identity and Affinity, manufactured by St. Jude Medical having their headquarters in St. Paul, Minnesota. As previously noted, a pacemaker may have a volume of about 11 cubic centimeters, or 11,000 cubic millimeters, which is about 366 times greater in volume than the claimed hollow cylindrical tube. Even the smallest

advertised pacemaker, the Identity DR5370 made by St. Jude Medical having a volume of 8000 cubic centimeters, would be 266 times greater in volume than the claimed hollow cylindrical tube.

The skilled person designing implantable devices, demanding hollow cylindrical tubes having inside diameters of about 1.78 mm would of course, not reference, nor refer to nor consult art that teaches volumes of devices from about 266 to 366 times greater. That certainly would be contrary to the design objective and actually would teach away from the claimed invention. The scaling down in size of the presently existing pacemakers to the size and shape of the claimed invention would render the pacemaker inoperable and consequently its function would not be maintained at such reduced size. The alternative proposed by the Examiner of using Schulman '367 gives little or no support to the Examiner's position, since the Examiner's starting point is Schulman '032 and with the disqualification of '032, Schulman '367 is never reached.

It is well recognized that a suggestion, teaching or motivation to combine prior art references is an essential evidentiary component of an obviousness holding. This showing must be clear and particular, and broad conclusory statements about the teachings of multiple references standing alone is not "evidence." This showing of a motivation to combine must be clear and particular and it must be supported by actual evidence. (Brown and Williamson Tobacco Corp. v. Philip Morris Inc., 229 F. 3rd 1120, 56 USPQ 2d 1456 (Fed. Cir. 2000). (Teleflex Inc. v. Ficosa North Am. Corp. 299 F. 3rd 1313) See also: Patents and the Federal Circuit, 6th edition, Robert Harmon, BNA Books, 2003, pp. 198-199,

Consistent with the rejections of all the claims in the application, the Examiner has failed to identify any teaching in Schulman '032 whatsoever that would comply with the imposed evidence requirement in order to support a finding of obviousness.

Attached herewith is the Declaration of Guangqiang Jiang, Ph.D. in support of Applicant's position regarding art cited by the Examiner. As the Examiner should note, Mr. Jiang considers Schulman "032 as an inappropriate reference that actually teaches away from the claimed invention.

Based on all of the foregoing, it is respectfully submitted that all the independent claims and those claims dependent thereon are patentable over the cited references and applicant respectfully requests withdrawal of all rejections and passage of the application to allowance. In the event the Examiner has questions and wishes to resolve them by telephone, please therefore contact the undersigned at 661-702-6812.

Respectfully Submitted,

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Date

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